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<p>(21) International Application Number: <b>PCT/EP99/00675</b></p> <p>(22) International Filing Date: <b>2 February 1999 (02.02.99)</b></p> <p>(30) Priority Data: 198 02 035.1 6 February 1998 (06.02.98) DE 198 19 896.5 5 May 1998 (05.05.98) DE</p> <p>(71) Applicant: <b>ROCHE DIAGNOSTICS GMBH [DE/DE]</b>; 116 Sandhofer Strasse, D-68305 Mannheim (DE).</p> <p>(72) Inventors: <b>GABEL, Rolf-Dieter</b>; Kurpfalzring 96, D-68723 Schwetzingen (DE). <b>MOECKEL, Jörn</b>; Hauptstrasse 46a, D-69221 Dossenheim (DE).</p> <p>(74) Agent: <b>WITTE, Hubert</b>; Grenzacherstrasse 124, CH-4070 Basle (CH).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report.</i></p>	
<p><b>(54) Title:</b> METERED DISPENSER</p> <p><b>(57) Abstract</b></p> <p>The present invention relates to a dosing dispenser for the alternating removal of two or more, possibly different solid forms of pharmaceutical substances to be taken, such as for example tablets, film tablets, coated tablets and/or capsules, which differ in their quantitative and/or qualitative composition.</p>			

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Metered Dispenser

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The present invention relates to a dosing dispenser for the alternating removal of two or more, 10 possibly different solid forms of pharmaceutical substances to be taken, such as for example tablets, film tablets, coated tablets and/or capsules, which differ in their quantitative and/or qualitative composition.

15 There are numerous examples of medicines for which, in the course of treatment, solid forms of different compositions are to be taken at different times, for example in the morning, evening or on different days. The composition of the formulation may 20 differ with respect to the dosage of the active substances, but it is also possible that the different formulations contain completely or partially different active substances. Examples of such medicines are combinations of daytime/nighttime tablets in the area 25 of painkillers and cough remedies, the two formulations containing partially or completely different active substances.

Also in widespread use are preparations for which different dosages of an active substance or else 30 of a number of active substances are contained in one pack. Examples of these are contraceptives, in particular, but also urological medicines. These 35 packs may be both so-called starter packs, with which a switch to the next highest dose is made after a few days, or monthly or calendar packs, with the aid of which physiological, cyclical increases in hormone levels are simulated.

Also popular are medicine packs in which, to encourage compliance or to make it easier for the 40 patient to take the correct dosage, not only active

formulations but also placebo formulations are contained. As a result, in the case of contraceptives for example, tablets can be taking continually, although for a certain time no hormones are to be 5 supplied (for example combination of 21 active and 7 placebo tablets - US 4,958,736).

For other groups of active substances too, for example for the use of biphosphonates for the treatment of osteoporosis, there are treatment regimens in which 10 even the daily changing of active and placebo formulations is envisaged (US 4,812,311).

To encourage patient compliance or to avoid mistakes in taking the medicine, the different tablets, film tablets, coated tablets, capsules etc. are 15 sometimes produced in different colours and/or are provided with embossed markings or imprints etc. In addition, they are arranged in "dosage rows" on blister strips and under certain circumstances are provided with numbers or indications of the day. Nevertheless, 20 mix-ups can occur, since elderly patients in particular have problems with reading lettering and there are often special requirements with respect to the correct regimen for taking medicine, and to this extent instances of uncertainty can be observed among 25 patients.

Greater certainty is offered by the so-called calendar packs, for example for contraceptives in the form of blister packs or dosage discs, on which, for example, the days of the week are marked. While in the 30 case of the dosage rows customary here (ascending or descending), the arrangement of a certain number of, for example, tablets of the same dosage, followed by a number of tablets of the next dosage is technically still quite simple to achieve, the daily changing 35 administration of two or more different formulations requires something more sophisticated. Here, at least special arrangements of the tablets on the blister pack and indications in the form of arrows etc. are

required, although this likewise cannot rule out mix-ups.

The invention was therefore based on the object of developing a reliable dosing dispenser with which 5 two or more possibly different individual pharmaceutical formulations with quantitatively and/or qualitatively different compositions can be taken alternately one after the other.

The object is achieved according to the 10 invention by the features of Claim 1. Expedient developments are contained in the subclaims. The novel device is characterized by at least two separate storage containers for quantitatively and/or qualitatively different solid pharmaceutical substances 15 to be taken which are arranged in a housing, which may have different forms. In the bottom of the housing there is either a catching device and/or at least one ejecting opening for the forms of medicine to be taken, it also being possible for the catching device to be 20 arranged outside the housing, for example in the form of a tray or similar vessels. Pharmaceutical substances may, for example, be in the form of tablets, film tablets, coated tablets and/or capsules. The ejecting opening has in this case the cross section of 25 the largest form which the medicine takes. The cross section of the housing is preferably rectangular, oval or circular, although combinations of these shapes are also feasible, for example one side of the dosing dispenser is rectangular, the other side is rounded 30 off. Other forms, such as polygonal, radial or trapezoidal housings, for example, can likewise be used.

The storage containers for the forms of medicine end on a movable dosing slide, which is 35 located above the bottom surface in the interior of the housing. This slide is constructed in analogy with the respective housing, likewise in a rectangular or oval design, for example in the form of a bar or plate, or for a cylindrical housing in a circular design, as a

dosage disc. It has as many receiving openings for the respective pharmaceutical substances from the storage containers as there are storage containers. The height of the dosing slide (thickness) is adapted to the 5 height of the forms of medicine, thereby preventing accidental adding of a second form of medicine to the dose. Furthermore, preferably arranged on the dosing slide are lugs which fix an end position and secure the forms of medicine to prevent accidental ejection from 10 the housing, as well as determine the filling and removal positions (click-stop positions).

The storage containers are elongated and preferably tubular and, depending on the form of medicine, may be round, oblong-shaped and/or 15 elliptical. To prevent accidental emptying upwards, they may be closed at the top, for example by fitting on plugs.

According to a design variant, the storage containers may be closed at the bottom by a movably 20 mounted plate or some other equivalent device when the dosing slide moves during emptying, in particular if three or more different forms of medicine are to be administered, and opened again during the filling operation when the dosing slide is moved back.

25 Preferred storage containers are those in which the different formulations are kept separately, which are filled once at the manufacturer's or are designed to be exchangeable or refillable (refill pack).

The device according to the invention may, in 30 addition, optionally be combined with mechanical, electromechanical and/or electronic devices which a) block the removal of the next dose for a certain time, for example by means of a built-in clock or the like, and/or 35 b) indicate the day, time of day, number, dosage or the like (by means of a day counter or a morning or evening indication) of the formulations just taken or the formulations to be taken next. In the simplest case, this may take place by inscriptions on the dosing slide

which become visible in an alternating manner through an opening in the housing wall. The changing of the indication takes place automatically when the dosing slide is pushed back and forth.

5 With this device according to the invention, the forms of medicine can be removed in a controlled sequence, with mix-ups avoided. In addition, the dosing dispenser according to the invention has the advantage that renewed filling is possible. For this purpose, if  
10 appropriate, a further slide which regulates the feeding of the forms of medicine is to be arranged in an analogous way above the storage containers.

Preferred design variants of the dosing dispenser according to the invention are described in  
15 more detail with reference to Figures 1 to 6, in which:

Figure 1 shows a rectangular dosing dispenser for the alternating removal of two different formulations, having one ejecting opening between the storage containers,

20 Figure 2 shows a cylindrical dosing dispenser for the alternating removal of two different formulations, having one ejecting opening between the storage containers,

Figure 3a shows a rectangular dosing dispenser  
25 for the alternating removal of three different formulations, having two ejecting openings,

Figure 3b shows a rectangular dosing dispenser for the alternating removal of three different formulations, having three ejecting openings,

30 Figure 4 shows a cylindrical dosing dispenser for the alternating removal of three different formulations, having two ejecting openings,

Figure 5 shows a rectangular dosing dispenser for the alternating removal of three different  
35 formulations, having one ejecting opening,

Figure 6 shows a rectangular dosing dispenser for the alternating removal of more than three different formulations, having a collecting tray.

According to Figure 1, two forms of pharmaceutical substance are accommodated in two separate tubular storage containers 1 and 2, which are located in a common housing 34 and are linearly arranged. The cross section of the tubes is adapted to the respective form of medicine. In this arrangement, the two storage containers may have the same cross section, but may also have different cross sections. The two storage containers end in an open manner on the dosing slide 31, which is located in the same housing 34. This dosing slide 31 has two receiving openings 11 and 12 for the forms of medicine, which correspond to the cross sections of the storage containers 1 and 2 and are arranged in such a way that, in the filling position, in each case one form of medicine slides into the corresponding dosing slide 31 and, in the emptying position, it falls downwards or is ejected out of the latter. The dosing slide 31 is covered at the bottom by a baseplate, which has an ejecting opening 21, which corresponds to the cross section of the form of medicine or to the cross section of the largest form of medicine (in the case of different formats). By moving the dosing slide 31 back and forth, in each case a bore 11 or 12 of the slide 31 is filled, while the content of the other bore is discharged through the opening 21 in the baseplate.

The dosing slide 31 is secured against accidental ejection from the housing 34 by suitable lugs. The two filling and removal positions are also fixed by these lugs. The ejection of the forms of medicine in the emptying position may be assisted, for example, by a spring-loaded spherical cap 33, which in the emptying position protrudes slightly from above into the corresponding receiving opening of the dosing slide 31. During the movement of the dosing slide, the spherical cap 33 slides resiliently back upwards against the resistance of a spring. Such a device also supports the exact positioning of the dosing slide 31. The tubular storage containers 1 and 2 may be closed

upwards against accidental emptying of the content, in the simplest case by pressing in plugs 32.

In another variant, in the upper part of the housing there is provided above the storage containers 5 a further dosing slide, which for filling is drawn partially out of the housing and thus permits the simultaneous or successive filling of the two tubes.

In analogy with the variant according to Figure 1, according to Figure 2 a cylindrical housing 34 is 10 used. Used as the dosing means is a circular dosage disc 31, which is likewise provided with two receiving openings 11 and 12, which correspond to the cross section of the forms of medicine to be discharged. Dosing and ejection are performed by turning the dosage 15 disc 31 back and forth. If appropriate, the end positions of the disc are marked again by correspondingly protruding lugs on the disc; alternatively, the dosage disc 31 may also have a greater diameter over part of its circumference, the 20 sides of the tongue bounding the stop positions.

Figure 3a represents an extended version of the variant according to Figure 1 in which three storage tubes 1, 2 and 3 are accommodated in a rectangular housing 34 and the dosing slide 31 contains three 25 receiving openings 11, 12 and 13, provided in a suitable way, for the controlled removal of different formulations, which are arranged, for example, in such a way that in the starting position the receiving openings 11 and 12 are filled. When the dosing disc 31 30 is then drawn out into the first click-stop position, the emptying of the receiving opening 11 takes place through ejecting opening 21. In the second click-stop position, the bore 12 is emptied through the second ejecting opening 22 and at the same time the receiving 35 opening 13 is filled. After the dosing slide 31 has been brought back into the starting position again, the content of the bore 13 is ejected through the opening 21 in the base. In this position of the dosing slide 31, the receiving openings 11 and 12 are simultaneously

filled again, etc. In a further variant according to Figure 3b, three ejecting openings 21, 22 and 23 are used.

As far as the arresting of the dosing slide 31 etc. is concerned, the same applies as was described for Figure 1.

In Figure 4, the dosing dispenser for the alternating dosing of three different formulations according to the variant as shown in Figure 3a is modified to the extent that the three tubular storage containers 1, 2 and 3 are accommodated in a cylindrical housing 34 and again a circular dosage disc is used as the dosing slide 31. The three receiving openings 11, 12 and 13 are arranged on a circular path, but at corresponding intervals, as in the case shown by Figure 3a.

According to Figure 5, as in the case of the variant shown by Figure 3a, three storage containers 1, 2 and 3 for the forms of medicine are arranged next to one another in a row. All three open out onto a dosing slide 31, which has three receiving openings 11, 12 and 13. By contrast with the variant 3a, the base of the housing 34 contains only one ejecting opening 21. In the starting position, all three receiving openings 11, 12 and 13 of the dosing slide 31 are filled simultaneously from the various storage tubes 1, 2 and 3. As soon as the dosing slide 31 is moved out of this starting position in the direction of the ejecting opening 21, a movably mounted plate (32a) closes the openings of the three storage containers 1, 2 and 3 in the downward direction, so that further sliding of the forms of medicine into the dosing slide 31 or a cavity possibly formed by the movement of the dosing slide is not possible. The dosing slide 31 may be drawn out of the housing 34 in three click-stopped stages, the forms of medicine being ejected one after the other at the individual stages out of the individual receiving openings 11, 12 and 13 through the opening 21. Once all three receiving openings 11, 12 and 13 in the

dosing slide 31 have been emptied, the latter is pushed back again into the starting position. During this operation, the closure plate beneath the three tubes 1, 2 and 3 is pushed back, for example by a mechanical follower or a lug on the dosing slide, and thus exposes the openings of the three tubes again. The three bores 11, 12 and 13 in the dosing slide 31 are re-filled etc.

5 In analogy with the variant shown in Figure 5, a further variant is concerned with a cylindrical housing 34, in which the three storage tubes 1, 2 and 3 are arranged circularly and not linearly. The circular dosing slide 31 again contains three receiving openings 11, 12 and 13. The base contains one ejecting opening 21. As soon as the dosing slide 31 is moved out of the 10 starting position, the three storage tubes 1, 2 and 3 are closed by means of a movable closure disc or the like, etc. Otherwise, the procedure described with 15 respect to Figure 5 applies.

Figure 6 offers a variant for more than three 20 different forms of medicine. In Figure 6, this is presented in the example of five different formulations.

The five different forms of medicine are 25 located in five storage containers 1 to 5. These are arranged diagonally in a rectangular housing. The tubes 1 to 5 open out onto a dosing device 31, which is in the form of a plate in which, in the starting position, the receiving openings 11 to 15 for the different forms of medicine are located exactly beneath 30 the storage containers 1 to 5. The dosing slide 31 may be drawn out forwards from the housing 34 in a click-stop manner in five stages, the individual receiving openings 11 to 15 being emptied one after the other. The forms of medicine fall into a common catching 35 device, for example a catching tray (20). The dosing slide 31 is subsequently pushed back into the starting position and the receiving openings 11 to 15 are filled again.

The dosing slide 31 must have an adequate length ("depth"), so that even in the fifth click-stop position, i.e. when the dosing slide 31 has been drawn out from the housing on one side to such an extent that 5 all the receiving openings 11 to 15 are visible, unintentional further sliding of the forms of medicine out of the storage containers 1 to 5 is prevented. Alternatively, the five storage containers may also be closed by a plate (32a) between the lower end of the 10 containers and the dosing slide 31 as soon as the dosing slide 31 is removed from the starting position.

The invention is not restricted to the exemplary embodiments described here. In particular, for example, two or more tubes per removal station are 15 also possible.

## List of reference numerals

1 = storage container for form of medicine 1  
2 = storage container for form of medicine 2  
3 = storage container for form of medicine 3  
4 = storage container for form of medicine 4  
5 = storage container for form of medicine 5  
n = storage container for form of medicine n

11 = receiving opening for form of medicine 1 in  
the dosing slide  
12 = receiving opening for form of medicine 2 in  
the dosing slide  
13 = receiving opening for form of medicine 3 in  
the dosing slide  
14 = receiving opening for form of medicine 4 in  
the dosing slide  
15 = receiving opening for form of medicine 5 in  
the dosing slide  
m = receiving opening for form of medicine m in  
the dosing slide

20 = catching means  
21 = ejecting opening  
22 = ejecting opening  
23 = ejecting opening

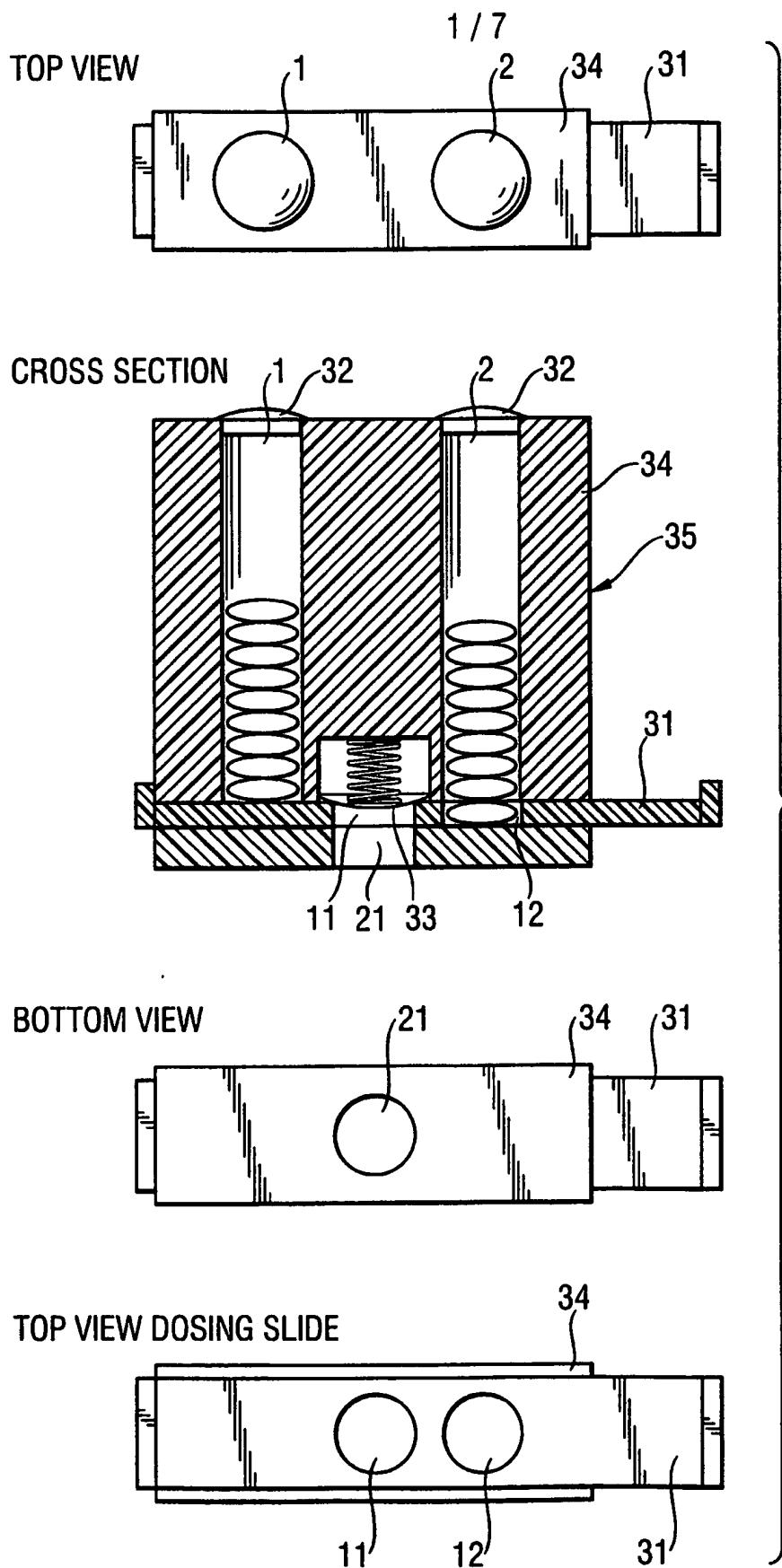
31 = dosing slide  
32,32a = closure for storage container  
33 = spring-loaded spherical cap  
34 = housing  
35 = dosing dispenser

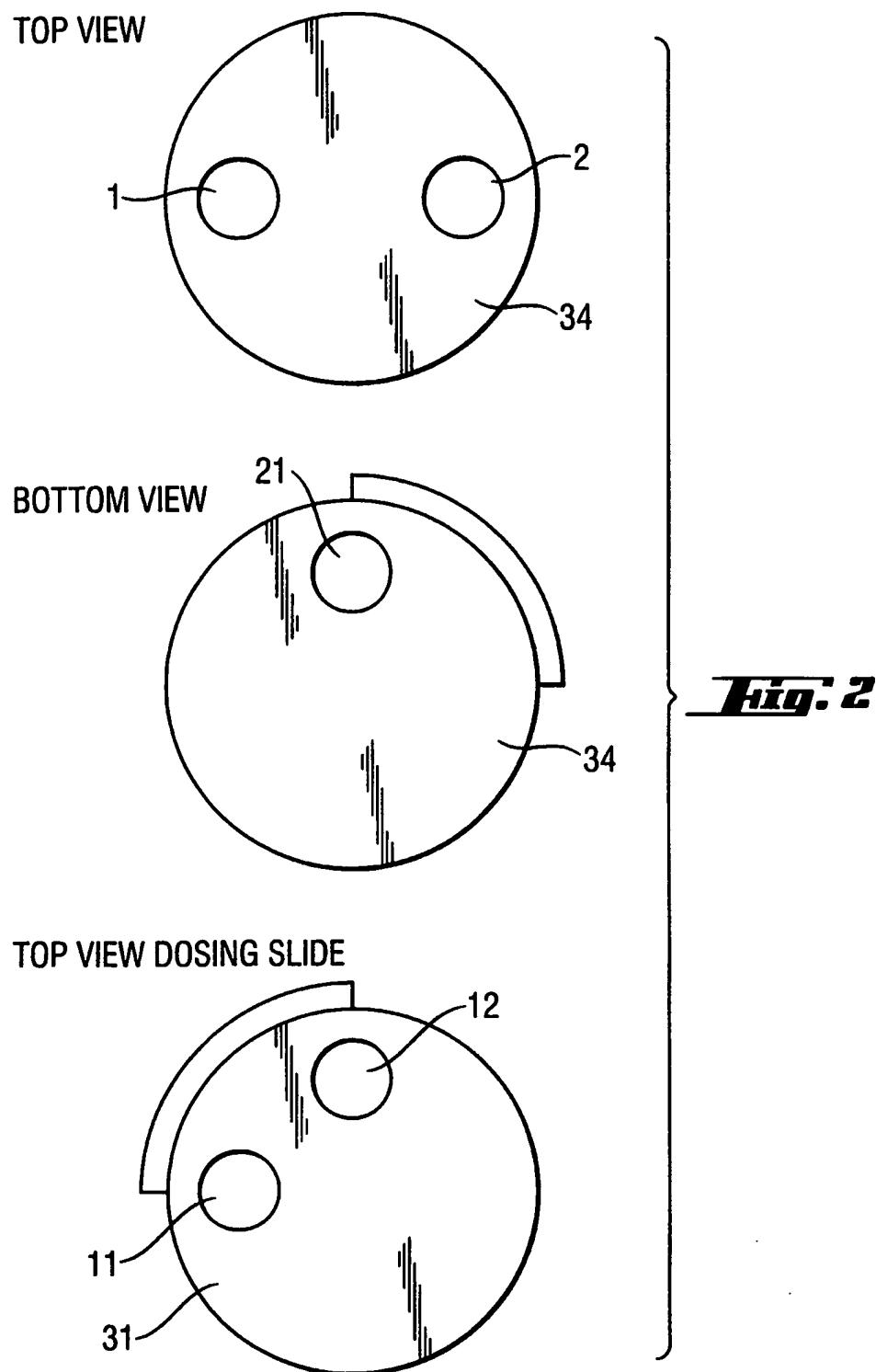
Patent claims

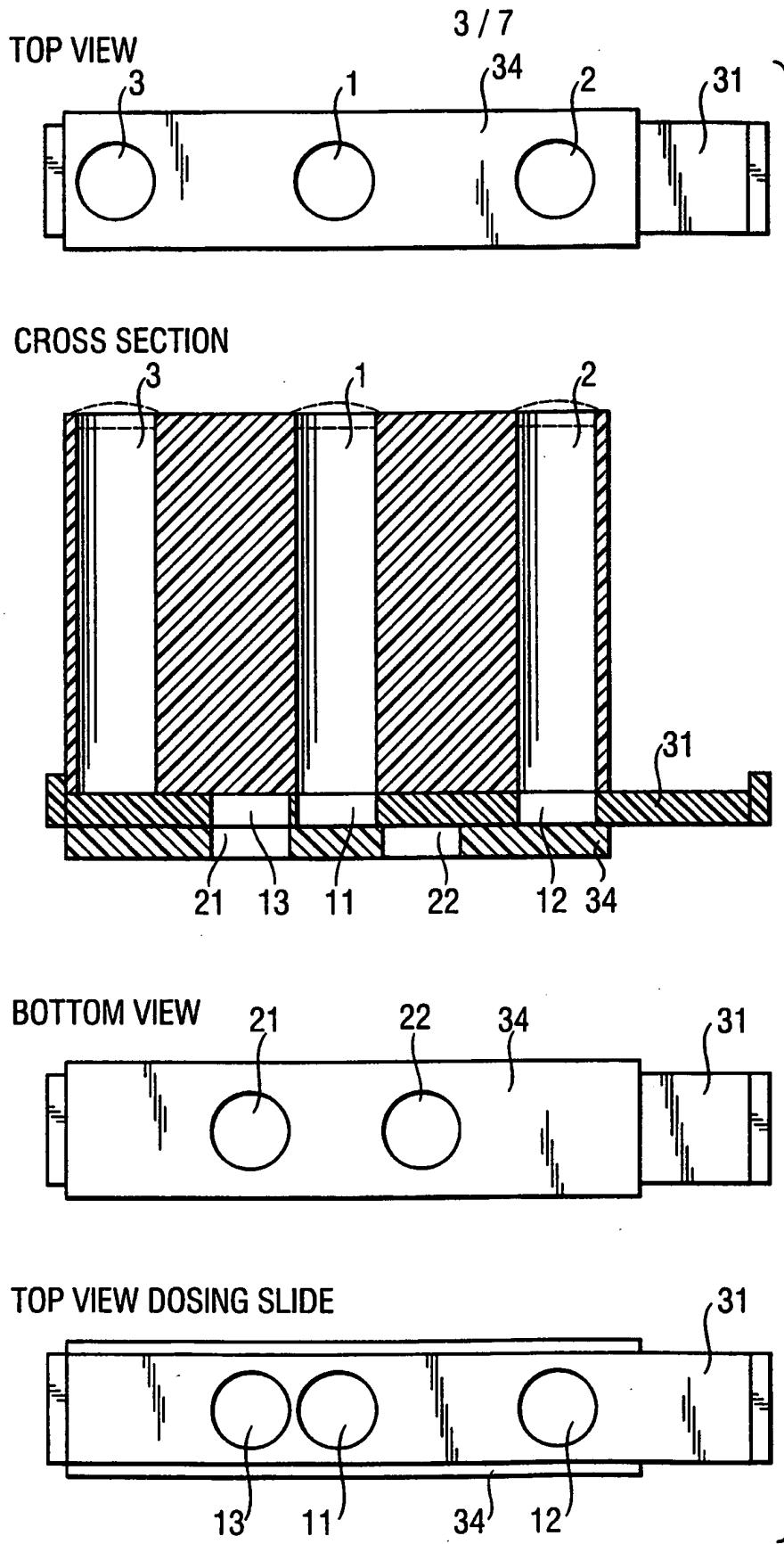
1. Dosing dispenser comprising at least two separate storage containers (1, 2, ... n) for at least two different solid forms of medicine to be taken which are arranged in a housing (34), in the bottom of which there is either a catching device (20) and/or at least one ejecting opening (21), and comprising a movable dosing slide (31) which is arranged beneath the storage containers and above the ejecting opening, has as many receiving openings (11, 12, ... m) for the forms of medicine as there are storage containers and which are arranged in the dosing slide in such a way that they can be placed under the storage containers.
- 15 2. Dosing dispenser according to Claim 1, characterized in that the storage containers are tubular, their cross sections being adapted independently of one another to the respective form of medicine.
- 20 3. Dosing dispenser according to Claim 1 or 2, characterized in that the cross sections of the storage containers are round, oblong-shaped and/or elliptical.
4. Dosing dispenser according to Claim 1, characterized in that the cross section of the housing (34) is rectangular, oval or circular.
- 25 5. Dosing dispenser according to Claim 1, characterized in that the dosing slide (31) is constructed in a way dependent on the housing (34) in a rectangular, oval or circular design and its thickness and its receiving openings are adapted to the respective forms of medicine.
- 30 6. Dosing dispenser according to Claim 1, characterized in that the ejecting opening (21) corresponds to the cross section of the largest form of medicine.
- 35 7. Dosing dispenser according one of Claims 1 to 6, characterized in that it comprises two storage containers (1) and (2) in a housing (34) with an ejecting opening (21) between the storage containers.

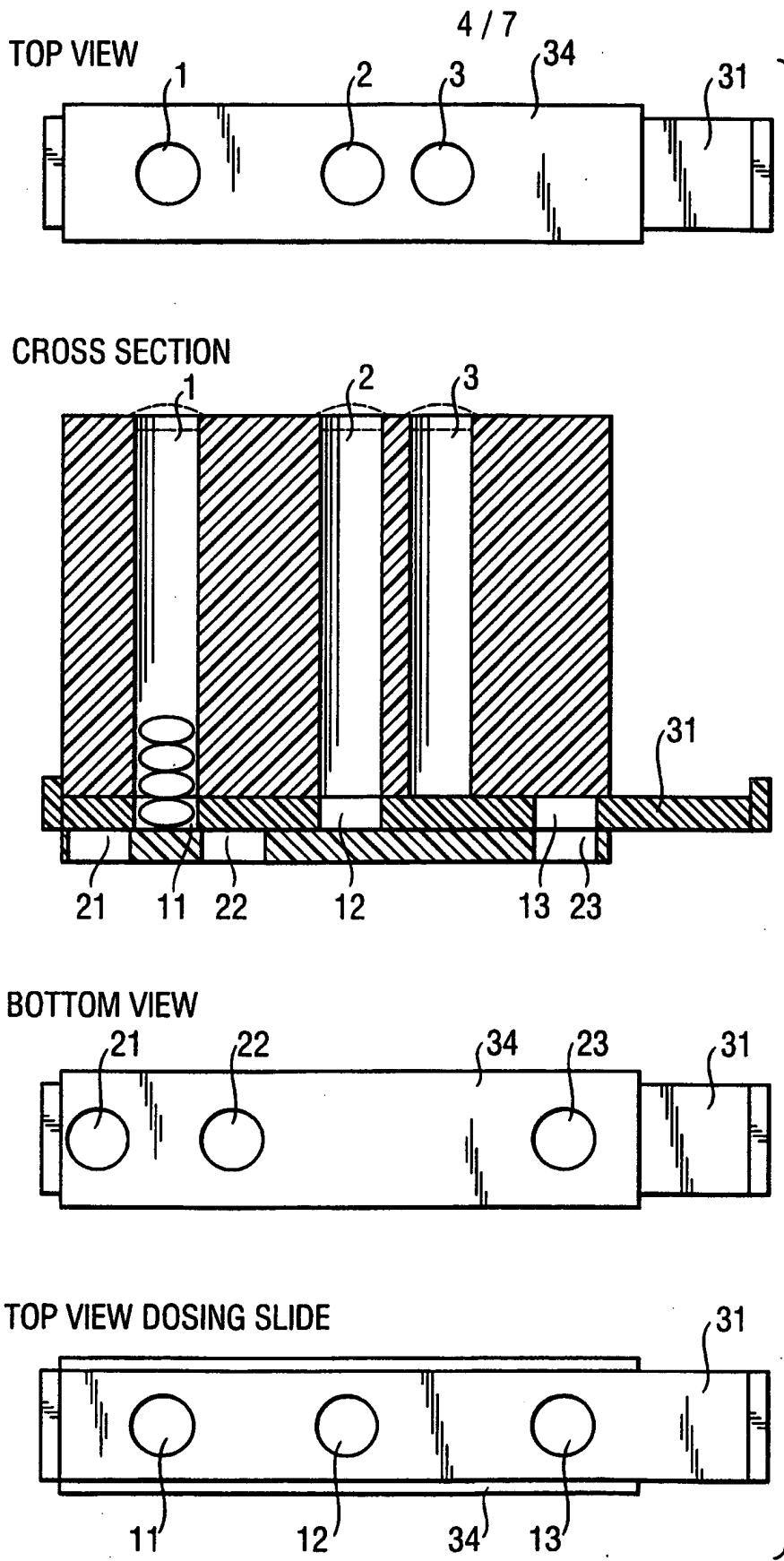
- 13 -

8. Dosing dispenser according to one of Claims 1 to 6, characterized in that it comprises three storage containers (1), (2) and (3) at equal intervals in a housing (34) with two ejecting openings (21) and (22).  
5 9. Dosing dispenser according to Claim 7 or 8, characterized in that the housing (34) is cylindrical and the ejecting openings (21) and possibly (22) are located in the edge region of the base.
10. Dosing dispenser according to one of Claims 1 to 6, characterized in that it comprises three storage containers (1), (2) and (3) at unequal intervals in a housing (34) with three ejecting openings (21), (22) and (23), openings (21) and (23) respectively being located on the outer walls of the housing.
- 15 11. Dosing dispenser according to one of Claims 1 to 7, characterized in that it comprises three storage containers (1), (2) and (3) in a housing (34) with an ejecting opening (21) between the housing wall and the first storage container.
- 20 12. Dosing dispenser according to one of Claims 1 to 7, characterized in that it comprises more than three storage containers which are arranged diagonally in a housing (34) and have either the same number of ejecting openings as storage containers or a catching device (20), which is arranged outside on the housing.
- 25 13. Dosing dispenser according to one of Claims 1 to 12, characterized in that it additionally includes an electromechanical device, such as for example a built-in clock for control.
- 30 14. Dosing dispenser according to one of Claims 1 to 13, characterized in that it is combined with a display, such as for example a day counter.

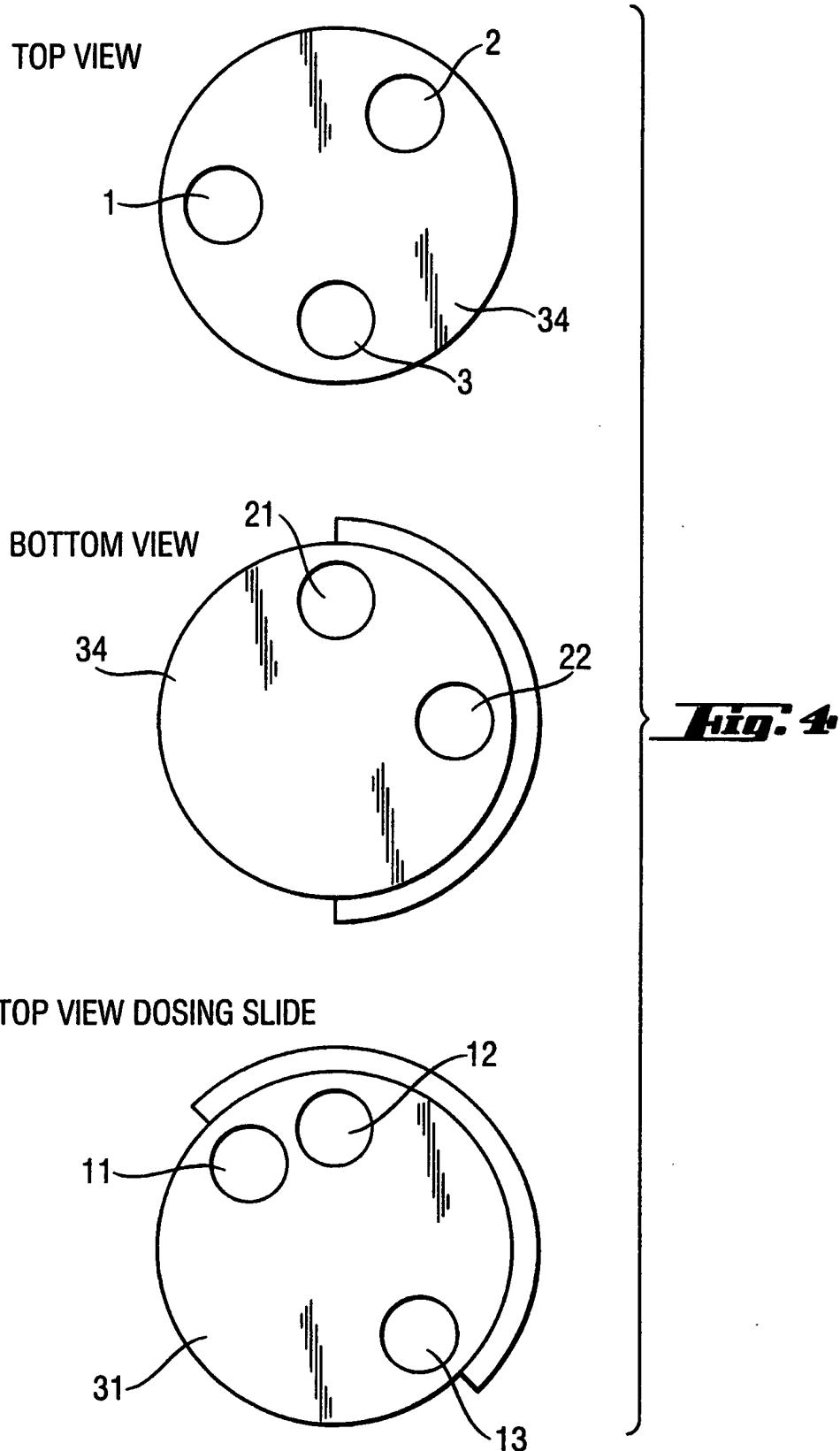


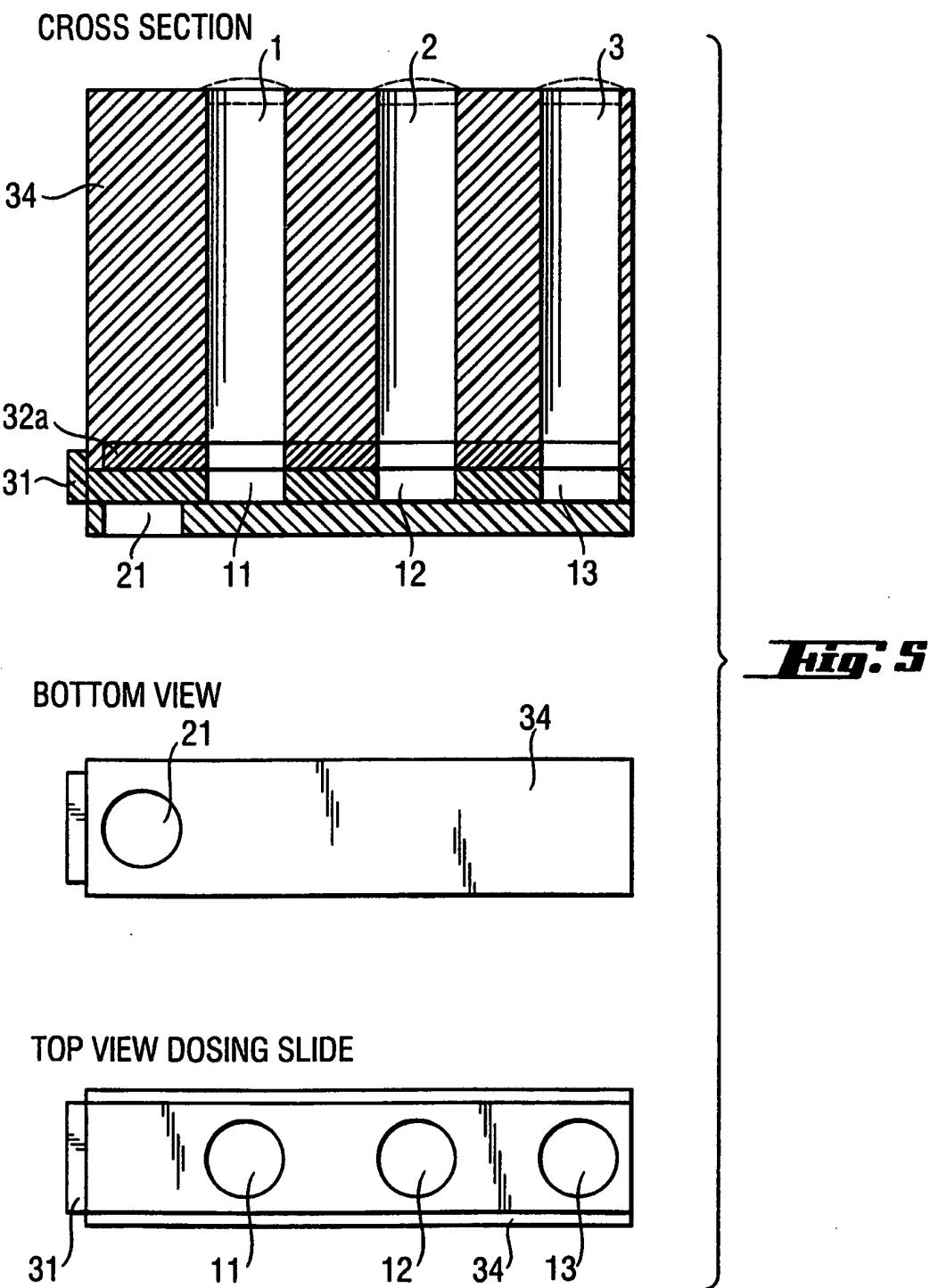


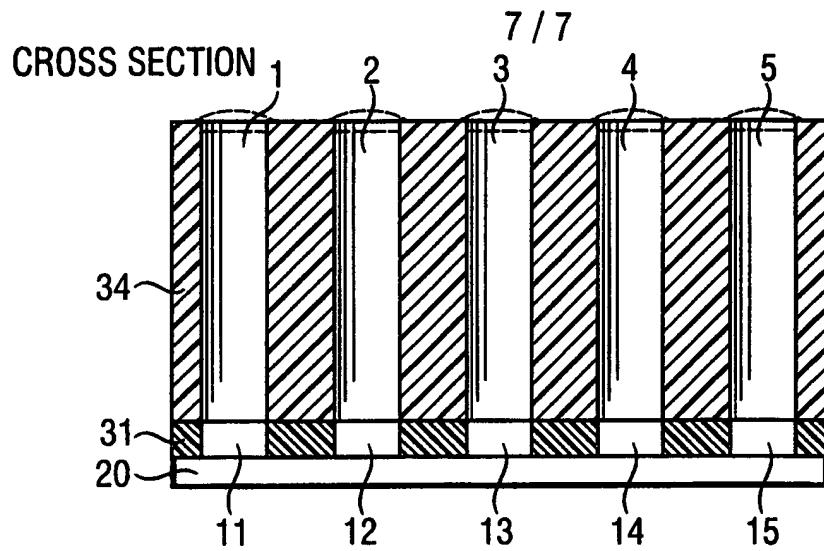


**Fig. 3b**

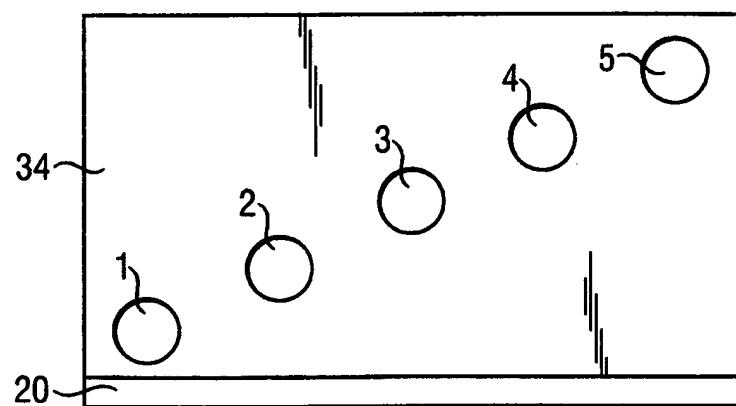
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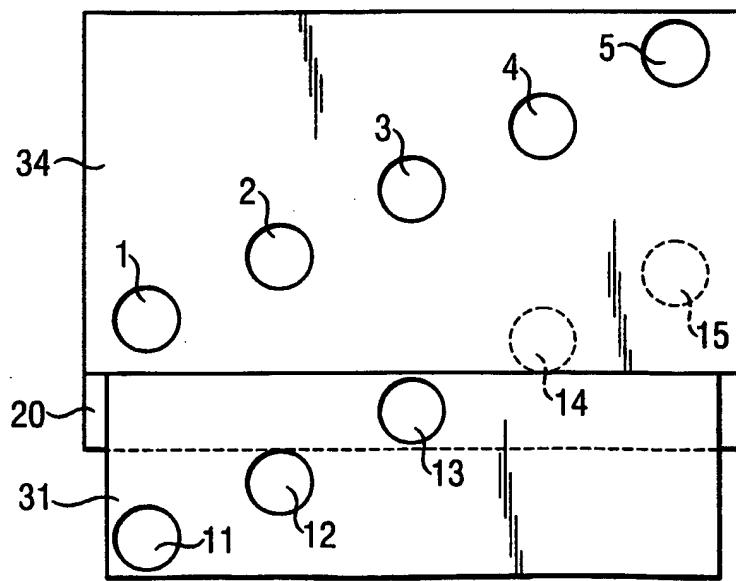




TOP VIEW

**Fig. 6**

TOP VIEW EMPTYING POSITION



# INTERNATIONAL SEARCH REPORT

Inte onal Application No  
PCT/EP 99/00675

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 B65D83/04 A61J7/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 B65D A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 42 05 112 A (BRACKMANN) 26 August 1993 see the whole document ---	1-6,13, 14
A	US 2 436 075 A (ORBAN) 17 February 1948 see column 1, line 27 - column 2, line 27; figures 1-4 ---	1
A	DE 31 43 953 A (HENKEL) 11 May 1983 see abstract; figure 1 -----	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

Date of mailing of the international search report

20 May 1999

28/05/1999

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Fax: (+31-70) 340-3016

Authorized officer

Lenoir, C

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/EP 99/00675

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4205112	A 26-08-1993	NONE	
US 2436075	A 17-02-1948	NONE	
DE 3143953	A 11-05-1983	NONE	